THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 36

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROY CURTISS III
and
GUY A. CARDINEAU

Appeal No. 93-4341
Application 07/398,520[1]

HEARD: January 11, 1996

Before SCHAFER, Vice Chief Administrative Patent Judge, and WINTERS and GRON, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

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[1] Application for patent filed August 29, 1989. According to applicants, the application is a continuation-in-part of Application 07/240,728, filed September 6, 1988, abandoned.

DECISION ON APPEAL

This appeal was taken from the examiner's decision refusing to allow claims 3, 6, 11 through 13, 15, 18, 23 through 25 and 50 through 52. Claims 26 through 49, which are the only other claims remaining in the application, stand withdrawn from further consideration by the examiner as directed to a non-elected invention.

Claims 13 and 50 are representative.

13. A composition suitable for eliciting a secretory immune response in a human or other animal which comprises a transgenic plant or material obtained from a transgenic plant, said transgenic plant comprising and expressing a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, said antigen or antigenic determinant being capable of eliciting a secretory immune response upon oral ingestion (emphasis added).

50. A transgenic plant which (a) expresses a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, and (b) induces a secretory immune response to Streptococcus mutans or Escherichia coli in a human or other animal, said immune response elicited by the antigen expressed in said plant.

The references relied on by the examiner are:

Gelvin	4,771,002	Sept. 13, 1988
Szybalski	4,774,182	Sept. 27, 1988
Gelfand et al. (Gelfand)	4,784,949	Nov. 15, 1988
Schaller et al. (Schaller)	4,894,332	Jan. 16, 1990
Dallas (Dallas '129) (European Patent Application)	0,060,129	Sept. 15, 1982
Curtiss (European Patent Application)	0,080,806	June 8, 1983

Russell-Jones et al. (Russell-Jones) (PCT)	WO 86/06635	Nov. 20, 1986
Goodman et al. (Goodman) (PCT)	WO 87/00865	Feb. 12, 1987

Walter S. Dallas and Stanley Falkow (Dallas), "Amino acid sequence homology between cholera toxin and Escherichia coli heat-labile toxin," 288 Nature no. 5790, 499-501, December 1980

Robert G. Holt, Yoshimitsu Abiko, Shigeno Saito, Maryla Smorawinska, Jeffrey B. Hansen and Roy Curtiss III (Holt), "Streptococcus mutans Genes That Code for Extracellular Proteins in Escherichia coli K-12," 38 Infection and Immunity no. 1, 147-56, October 1982

John D. Clements, Frank L. Lyon, Karin L. Lowe, Allen L. Farrand and Sawsan El-Morshidy (Clements), "Oral Immunization of Mice with Attenuated Salmonella enteritidis Containing a Recombinant Plasmid Which Codes for Production of the B Subunit of Heat-Labile Escherichia coli Enterotoxin, 53 Infection and Immunity no. 6, 685-92, September 1986

H.J. de Aizpurua and G.J. Russell-Jones (Aizpurua), "Oral Vaccination -- Identification of Classes of Proteins that Provoke an Immune Response upon Oral Feeding," 167 The Journal of Experimental Medicine no. 2, 440-51 (February 1988)

The issues presented for review are:

(1) whether the examiner erred in rejecting claims 3, 11 through 13, 15, 23 through 25 and 50 through 52 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Schaller, Gelfand, Gelvin, Szybalski, Goodman and Aizpuruà; and

(2) whether the examiner erred in rejecting claims 3, 6, 11 through 13, 15, 18, 23 through 25 and 50 through 52 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of

Schaller, Gelfand, Gelvin, Szybalski, Goodman, Dallas '129, Clements, Holt, Dallas, Curtiss, Russell-Jones, and Aizpurua.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials:

(1) the instant specification, including Figures 1 through 12, and all of the claims on appeal;

(2) appellants' Brief before the Board;

(3) the Examiner's Answer; and

(4) the prior art references cited and relied on by the examiner.

On consideration of the record, including the above-listed materials, we affirm the examiner's rejections of claims 13, 15, 18, and 23 through 25. We reverse the rejections of claims 3, 6, 11, 12, and 50 through 52. Our reasoning is set forth below.

DISCUSSION

Initially, with respect to each ground of rejection under 35 U.S.C. § 103, we observe that appellants group all of the appealed claims as standing or falling together. See the Brief before the Board, page 4, section entitled "GROUPING OF

CLAIMS." Nevertheless, on reflection, we conclude that independent claims 13 and 50 present separate questions of patentability which must necessarily be treated separately. Accordingly, for the purposes of this appeal, we have treated dependent claims 15, 18, and 23 through 25 as standing or falling together with independent claim 13. Likewise, we have treated dependent claims 3, 6, 11, 12, 51 and 52 as standing or falling together with independent claim 50.

Claims 13, 15, 18 and 23 through 25

During patent examination, the pending claims must be interpreted as broadly as their terms reasonably allow. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Here, claim 13 defines a composition suitable for eliciting a secretory immune response in a human or other animal which comprises a transgenic plant or material obtained from a transgenic plant, said transgenic plant comprising and expressing a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, said antigen or antigenic determinant being capable of eliciting a secretory immune response upon oral ingestion. That claim embraces not only a transgenic plant, but also material "obtained

from" or "derived from" a transgenic plant. See appellants' Brief before the Board, page 3, second paragraph. Giving the claim its broadest reasonable interpretation, we hold that claim 13 "reads on" a colonization antigen per se, for example, an antigen selected from the group consisting of SpaA, GtfB, dextranase, K88, K99, and CFA. In so holding, we observe that this claim is couched in product-by-process language, i.e., the claim recites a final product ("material") obtained from a source material ("transgenic plant"). As stated in In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985), even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself and the patentability of a product does not depend on its method of production. We further observe that, on this record, appellants have presented no evidence establishing that a colonization antigen of Streptococcus mutans or Escherichia coli obtained from a transgenic plant differs from a colonization antigen of Streptococcus mutans or Escherichia coli obtained from traditional source materials.

We find that each of the colonization antigens SpaA, GtfB, dextranase, K88, K99, and CFA was known in the art at the time appellants' invention was made. Merely by way of example,

see the acknowledged prior art discussed in appellants' specification, pages 13, 14, and 24 through 26. Also, see the Aizpurua, Holt, and Dallas '129 references cited and relied on by the examiner. Accordingly, we find that claim 13 is anticipated within the meaning of 35 U.S.C. § 102 by the acknowledged prior art, Aizpurua, Holt, or Dallas '129.

A lack of novelty in the claimed subject matter is the "ultimate or epitome of obviousness." Jones v. Hardy, 727 F.2d 1524, 1529, 220 USPQ 1021, 1025 (Fed. Cir. 1984); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982); In re May, 574 F.2d 1082, 1089, 197 USPQ 601, 607 (CCPA 1978); In re Pearson, 494 F.2d 1399, 1402, 181 USPQ 641, 644 (CCPA 1974). On that basis, we affirm the examiner's rejections of claim 13 under 35 U.S.C. § 103. As previously indicated, claims 15, 18, and 23 through 25 fall together with claim 13.

Though we sustain the rejections of claim 13 under 35 U.S.C. § 103, nevertheless, our reasoning differs substantially from that set forth by the examiner. On these facts, the "basic thrust of the rejection" at the examiner and Board level is not the same. See In re Kronig, 539 F.2d 1300, 1303, 190 USPQ 425, 427 (CCPA 1976). Accordingly, appellants may treat our affirmance as though it were a new ground of rejection under the provisions of 37 CFR § 1.196(b).

Claims 3, 6, 11, 12, and 50 through 52

Independent claim 50 defines a transgenic plant which (a) expresses a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, and (b) induces a secretory immune response to Streptococcus mutans or Escherichia coli in a human or other animal, said immune response elicited by the antigen expressed in said plant. Having reviewed the combined teachings of the references relied on by the examiner, we find that the references are clearly insufficient to support a conclusion of obviousness of claims containing those limitations.

Schaller discloses the use of host cells as mini-factories to produce an antigenic protein, which is extracted from the cells and administered by traditional means to an animal or human. Schaller does not disclose transforming whole plants to produce antigenic proteins. The examiner's position to the contrary, notwithstanding, Schaller does not teach or suggest the "expression of surface antigens of pathogenic organisms in transformed plants." See the Examiner's Answer, page 4. Nor does Schaller teach the expression of a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli. This "primary" reference discloses (1) using host cells, for example, plant cells in

tissue culture, as mini-factories to produce an antigenic protein, and (2) extracting the antigen from the cells for administration to an animal or human by traditional means. See particularly Schaller, column 1 in its entirety, and column 7, lines 7 through 24. Schaller does not teach or suggest a transgenic plant which (a) expresses a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, and (b) induces a secretory immune response to Streptococcus mutans or Escherichia coli in a human or other animal, said immune response elicited by the antigen expressed in said plant.

Gelfand discloses a modified, truncated gene sequence integrated into plasmids for incorporation into procaryotic and eucaryotic host cells. Though Gelfand teaches that plant cells are available as hosts, nevertheless, the very same portion of the reference makes clear that "it is also, of course, possible to express genes encoding polypeptides in eucaryotic host cell cultures derived from multicellular organisms" (emphasis added). See Gelfand, column 12, lines 3 through 23. Again, the use of plant cells in tissue culture as mini-factories to produce antigens does not suggest the transformation of whole plants to express antigen. The examiner's position to the contrary,

notwithstanding, Gelfand does not disclose "means of making transgenic plants." See the Examiner's Answer, page 4. Therefore, Gelfand does not remedy any of the deficiencies of the "primary" reference Schaller.

Gelvin constitutes closer prior art than Schaller or Gelfand, because Gelvin discloses a method of transforming whole plants. Nevertheless, Gelvin teaches transforming plants to improve the genetic characteristics of the plant and not to express a specific antigen which induces a secretory immune response in a human or other animal. See Gelvin, particularly column 15, lines 3 through 64. Gelvin does not disclose or suggest a transgenic plant which expresses a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, or which expresses DNA coding for any specific antigen that would stimulate secretory immunity in an animal or human upon ingestion of the plant. Gelvin, therefore, does not remedy the deficiencies of Schaller or Gelfand.

Szybalski, like Gelvin, discloses transforming whole plants to improve the genetic characteristics of the plant. Szybalski teaches conferring immunity from infectious disease on a host plant, but does not teach expressing DNA coding for an antigen in a transformed plant host for the purpose of conferring

immunity in an animal or human upon ingestion of the plant. Szybalski does not remedy the deficiencies of Schaller, Gelfand, or Gelvin, and does not disclose or suggest a transgenic plant which (a) expresses a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, and (b) induces a secretory immune response to Streptococcus mutans or Escherichia coli in a human or other animal, said immune response elicited by the antigen expressed in said plant.

Goodman discloses transforming plants to function as mini-factories for the production of mammalian proteins, which are extracted from the plants for administration in the traditional manner. Goodman further suggests that, in some instances, it may be neither necessary nor desirable to extract and isolate the mammalian protein product from the plant. Where the product can have a physiological effect on ingestion, Goodman discloses, it may be sufficient that the product be retained within the plant. This will be true where the plant part is edible. See Goodman, paragraph bridging pages 9 and 10. However, Goodman does not disclose or suggest retaining in the plant a protein which has no effect on ingestion. Like all of the references discussed above, Goodman does not disclose or suggest a transgenic plant which (a) expresses a DNA sequence coding for a

colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, and (b) induces a secretory immune response to Streptococcus mutans or Escherichia coli in a human or other animal, said immune response elicited by the antigen expressed in said plant.

The Aizpurua reference, entitled "Oral Vaccination," discloses the identification of classes of antigens which, when orally administered to an animal at low doses, were effectively taken up by the cells of the gastrointestinal mucosa and were able to elicit serum and/or secretory antibodies without the induction of systemic tolerance. See particularly Aizpurua, page 441, first full paragraph. Aizpurua, however, does not disclose or suggest a transgenic plant. Aizpurua, in combination with the references discussed above, does not disclose or suggest a transgenic plant which (a) expresses a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli, and (b) induces a secretory immune response to Streptococcus mutans or Escherichia coli in a human or other animal, said immune response elicited by the antigen expressed in said plant.

In the examiner's first rejection under 35 U.S.C. § 103, three of the six references cited against the claimed

invention disclose transgenic plants, namely, Gelvin, Szybalski, and Goodman. None of those references, however, discloses or suggests a transgenic plant which induces a secretory immune response to Streptococcus mutans or Escherichia coli or provides an oral vaccination. The one reference included in this rejection which discloses oral vaccination, Aizpurua, does not disclose or suggest a transgenic plant. On these facts, we find that there is no teaching, suggestion, or motivation to combine the references in the manner proposed by the examiner, other than hindsight gained by knowledge of the claimed invention. As stated in In re Kamm, 452 F.2d 1052, 1055, 172 USPQ 298, 301 (CCPA 1972), a basic mandate inherent in 35 U.S.C. § 103 is that piecemeal reconstruction of prior art references in light of appellants' disclosure shall not be the basis for a holding of obviousness. For these reasons, we conclude that the examiner has not established a prima facie case of obviousness of claim 50 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Schaller, Gelfand, Gelvin, Szybalski, Goodman and Aizpurua.

We have not overlooked the second rejection under 35 U.S.C. § 103, or the six additional references relied on by the examiner in setting forth that rejection. However, we find

no teaching or suggestion in the six additional references that plants be transformed to express a DNA sequence coding for a colonization antigen or antigenic determinant thereof, of Streptococcus mutans or Escherichia coli. Nor do the additional references provide any suggestion of a transgenic plant which induces a secretory immune response to Streptococcus mutans or Escherichia coli in a human or other animal. Accordingly, we conclude that the examiner has not established a prima facie case of obviousness of claim 50 under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Schaller, Gelfand, Gelvin, Szybalski, and Goodman, in view of Dallas '129, Clements, Holt, Dallas, Curtiss, Russell-Jones, and Aizpurua.

CONCLUSION

For these reasons, we sustain both rejections of claim 13 under 35 U.S.C. 103. Claims 15, 18, and 23 through 25 fall together with claim 13.

We do not, however, sustain the rejections of claim 50 under 35 U.S.C. § 103. Claims 3, 6, 11, 12, 51, and 52 stand together with claim 50.

Accordingly, the examiner's decision is affirmed-in-part.

Any request for reconsideration or modification of this decision by the Board of Patent Appeals and Interferences based upon the same record must be filed within one month from the date of the decision (37 CFR § 1.197). Should appellants elect to have further prosecution before the examiner in response to the new rejection under 37 CFR § 1.196(b) by way of amendment or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire two months from the date of this decision.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART 37 CFR 1.196(b)

RICHARD E. SCHAFER
Vice Chief Administrative Patent Judge)
)
)
SHERMAN D. WINTERS)
Administrative Patent Judge) BOARD OF PATENT
) APPEALS AND
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Appeal No. 93-4341
Application 07/398,520

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